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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,487

11/09/2006

Michael Cahill

27581U

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20529 7590 09/14/2009  
THE NATH LAW GROUP  
112 South West Street  
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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

09/14/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,487	<b>Applicant(s)</b> CAHILL ET AL.	
	<b>Examiner</b> MEERA NATARAJAN	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 5-28,31-33,37-49 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,29,30 and 50-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/01/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendments in the reply filed on 06/01/2009 is acknowledged and entered into the record.
2. Accordingly, Claims 1-53 are pending. Claims 5-27, 37-49 and 53 are withdrawn as being drawn to non-elected inventions/species. As stated in the previous office action, Claims 28 and 31-33 require at least two diagnostic markers, however Applicant has only elected one, Annexin A3, therefore claim 28 and dependent claims 31-33 are withdrawn.
3. Claims 1-4, 29, 30, 34-36 and 50-52 will be examined on the merits.

### ***Claim Rejections Maintained - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1-4, and 29, 30, 34-36, 50-52 are incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or

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visualized, and a correlation step describing how the results of the assay allow for the determination. The claims are drawn to detecting annexin A3 protein as compared to a control. The claims however do not recite a correlation step indicating how the level of annexin A3 as compared to a control correlates to the diagnosis of prostate cancer.

Clarification is required.

***Claim Rejections Maintained - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 29, 30, 34-36 and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Schlegel et al. (PgPub 20030108963, published June 12, 2003, filed 07/25/2002).

9. The claims are drawn to a method of diagnosing prostate cancer comprising detecting the level of annexin A3 protein as compared to a control. Schlegel et al. teach methods for detecting and diagnosing human prostate cancer. Schlegel et al. disclose diagnostic markers, including annexin A3 (see Tables 1-4), are particularly useful in both screening for the presence of prostate cancer as well as for metastatic potential of prostate cancer (see paragraph [0011]). Schlegel et al. also discloses the use of

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antibodies which specifically bind to the marker proteins (i.e. annexin A3) for diagnostic purposes and a kit (see paragraph [0012-13].

### ***Response to Arguments***

10. Applicants argue Schlegel et al. only show differential expression of annexin A3 RNA and therefore fail to teach how annexin A3 protein should be used as a diagnostic marker. This argument has been carefully considered but now found persuasive. As stated in the 102(e) rejection set forth above, Schlegel et al. teach methods for detecting and diagnosing human prostate cancer by identifying specific markers such as Annexin A3. Schlegel et al. disclose the "markers" can be a gene with an altered level of expression, a nucleic acid encoded by or corresponding to a marker of the invention, and a marker protein encoded by or corresponding to a marker of the invention (see paragraph [0072]). Claim 8 of Schlegel et al. is broadly interpreted to be a method of assessing whether a patient is afflicted with prostate cancer comprising detecting the level of expression of a "marker" in a patient sample, wherein the "marker" is either gene expression, nucleic acid expression, or protein expression. Schlegel et al. supports the detection of annexin A3 protein by the disclosing the use of antibodies which specifically bind to the markers proteins. Therefore, the rejection of record is maintained.

### ***Conclusion***

11. Claims 1-4, 29, 30, 34-36 and 50-52 are rejected.
12. No Claim is allowed.

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13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MEERA NATARAJAN** whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643